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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/638,426	08/12/2003	Samuel J. Epstein	12013/47601	5077

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EXAMINER	
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ART UNIT	PAPER NUMBER
3763	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/638,426	EPSTEIN ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER D. KOHARSKI	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,19,20,22-35 and 40-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 19-20, 22-35, and 40-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgements

The Examiner acknowledges the reply filed 06/16/2009 in which claims 1 and 19 were amended and new claims 41-42 were added. Currently claims 1, 19-20, 22-35 and 40-42 are pending for examination in this application. Additionally, the Examiner also acknowledges the amendments to the specification filed 6/16/2009.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 19-20, 22-33, 34-35, 40-41, 44 and 46 are rejected under 35 U.S.C 103(a) as being unpatentable over Ahn (US2002/0077687) in view of Zarate (USPN5,662,619).

Regarding claims 1, 19-20, 22-32, 34-35, 40-41, 44 and 46, Ahn discloses a device (Figure 5) and method capable of direct delivery of a shear thickening fluid (cell

suspension of viscous fibrin ([0010, 0041, 0043, 0045]) (see Sierra et al. USPN, 5290,552 (example 5), showing that fibrin compositions exhibit shear thickening behaviors as noted in the office action dated 04/28/2009) having therapeutic properties from a pharmaceutically active ingredient ([0043]) to a target site (heart 10), the device comprising: a channel having a proximal end, a distal end and a central lumen extending therethrough (lumen through injection needle 44), the central lumen having a longitudinal axis, the channel containing a shear thickening fluid having therapeutic properties ([0010]), wherein the channel contains a single oval flow orifice (near 46).

Ahn meets the claim limitations as described above except for the viscosity adjusters.

However, Zarate teaches a venous needle.

Regarding claims 1, 19-20, 22-33, 34-35, 40-41, 44 and 46, Zarate teaches a device (Figures 3-4, 12) comprising: a channel having a proximal end, a distal end and a central lumen (within needle 12) extending therethrough (lumen through injection needle 12), the central lumen having a longitudinal axis the channel configured to expose the shear thickening fluid to a viscosity adjuster (28, 30); and wherein the viscosity adjuster comprises at least two non-overlapping post or peg-like projections (28, 30) extending substantially perpendicularly from one or more walls (near 22) that are directly opposed to each other (i.e. across from each other via a vertical axis, and/or opposite to each other via an axis through each of the projections) of the channel and leaving an open continuous straight flow channel coincident with the central lumen's

longitudinal axis, wherein the device further comprising circular flow orifices (20, Figures 3-4).

At the time of the invention, it would have been obvious to include the projections of Zarate with needle of Ahn in order to add a mechanism for even injection distribution through the needle orifice (near 51). The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Zarate (cols 1-2)

Claim Rejections - 35 USC § 103

Claim 42 is rejected under 35 U.S.C 103(a) as being unpatentable over Ahn (US2002/0077687) in view of Zarate (USPN5,662,619).

Regarding claim 42, Ahn as modified by Zarate discloses the claimed invention except for projections being constructed from nitinol, Teflon® or stainless steel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the needle and projections from stainless steel, nitinol or Teflon® since all are well known biocompatible materials and since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).*

Claim Rejections - 35 USC § 103

Claims 1, 19, 43 and 45 are rejected under 35 U.S.C 103(a) as being unpatentable over Ahn (US2002/0077687) in view of Zarate (USPN5,662,619).

Regarding claims 1, 19, 43 and 45, Ahn discloses a device (Figures 4 and 12) and method capable of direct delivery of a shear thickening fluid (cell suspension of viscous fibrin ([0010, 0041, 0043, 0045]) (see Sierra et al. USPN, 5290,552 (example 5), showing that fibrin compositions exhibit shear thickening behaviors as noted in the office action dated 04/28/2009) having therapeutic properties from a pharmaceutically active ingredient ([0043]) to a target site (heart 10), the device comprising: a channel having a proximal end, a distal end and a central lumen extending therethrough (lumen through injection needle 44), the central lumen having a longitudinal axis, the channel containing a shear thickening fluid having therapeutic properties ([0010]), wherein the channel contains a orifice (distal open end of 44, Figure 12).

Ahn meets the claim limitations as described above except for the viscosity adjusters.

However, Nilsson et al. teaches a catheter for peritoneal dialysis.

Regarding claims 1, 19, 43 and 45, Nilsson et al. teaches a device(28) (Figures 3, 6 and 7) comprising: a channel (along axis near 21) having a proximal end, a distal end and a central lumen (near 21) extending therethrough (lumen through catheter 28), the central lumen having a longitudinal axis the channel configured to expose the shear thickening fluid to a viscosity adjuster (42); and wherein the viscosity adjuster comprises at least two non-overlapping post or peg-like projections (42) extending substantially

perpendicularly from one or more walls (of catheter 28) that are directly opposed to each other (i.e. across from each other via a vertical axis, and/or opposite to each other via an axis through each of the projections) of the channel and leaving an open continuous straight flow channel coincident with the central lumen's longitudinal axis, wherein the device further comprises a circular flow orifice (17, Figure 7).

At the time of the invention, it would have been obvious to incorporate the projections (42) of Nilsson et al. to the system of Ahn in order to add a distal flow control element to control the distal tip flow rate. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Nilsson et al. (cols 1-2).

Response to Arguments

Applicant's arguments filed 12/08/2009 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Ahn reference does not disclose a shear thickening fluid and it would not be obvious to incorporate the projections of Zarate to the system of Ahn.

The Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Regarding the Ahn reference, the Final office action 04/28/2009 disclosed the Sierra et al. USPN, 5290,552 (example 5) reference, which discloses that fibrin compositions exhibit shear thickening behaviors. Therefore the fibrin delivery system of

Ahn is disclosed as delivering a shear thickening fluid. Regarding the combination of the Ahn and Zarate, the Examiner asserts that the combination is proper as Zarate teaches a mechanism for adjusting flow through a channel and for diverting fluid flow through an orifice.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 03/08/2010

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763